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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,519	12/14/2001	Betty Wu	10255-028-999	3927

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,519

Applicant(s)

WU ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,9,12-14,16-19,21-23,25-30,32,33 and 35-44 is/are pending in the application.
- 4a) Of the above claim(s) 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,9,12-14,16-19,21-23,25-30,32,33,35-37 and 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/14/2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) .
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 4, 9, 12 – 14, 16 – 19, 21 – 23, 25, 26, 39 & 40 – 44 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 1, 16 & 39, the recited term “thermopneumatic actuator” or “thermopneumatic gas actuator” does not appear to be found or explicitly defined in the specification. Regarding claim 40, process of “thermopneumatically moving a cell-containing liquid...” also does not appear to be described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 28, it is unclear as to what structure or claim limitation the claim is referring. The claim is referring to the downstream surface of what structure?

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the recited “thermopneumatic actuator” or “thermopneumatic gas actuator” must be shown and labeled or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

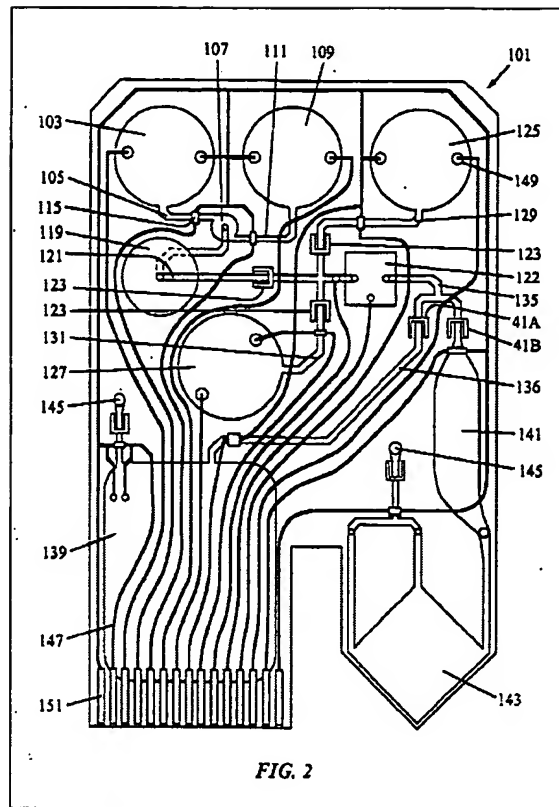
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 4, 9, 12 – 14, 16 – 19, 21 – 23, 25 – 30, 32, 33, 35 – 37 & 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al. (U.S. Pat. Pub. No. US 2002/0055167 A1) (hereinafter “Pourahmadi”) in view of Handique et al. (U.S. Pat. No. 6,130,098 A) (hereinafter “Handique”).

Regarding claims 1, 9, 12, 13, 16, 23, 26 & 39, Pourahmadi teaches an apparatus (cartridge 101) comprising: a sample port (103); a channel (105); and a lysing zone (lysing chamber 119) (see paragraph 0048; figure 2).

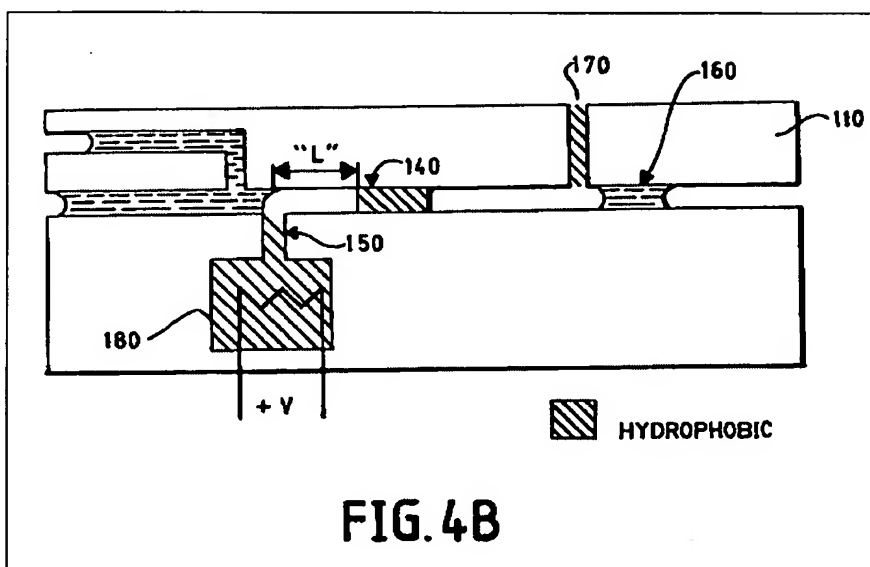


Pourahmadi does not specifically teach the further incorporation of a gas actuator comprising a thermopneumatic actuator and an associated vent structure to facilitate sample fluid flow within the disclosed apparatus. Pourahmadi does teach that a fluid sample may be introduced into the cartridge by a variety of means, manual or automated (see paragraph 0078). Pourahmadi teaches that for automated sample introduction, additional cartridge design features are employed and, in many cases, impart specimen accession functionality directly into the cartridge (see paragraph 0080). Pourahmadi does further teach that a fluid motive source comprising a pneumatic pressure source can be internally incorporated within the cartridge apparatus for facilitating sample fluid transport (see paragraph 0067).

Handique teaches a thermopneumatic apparatus for facilitating fluid transport in microfluidic devices (see col. 13, line 60 – col. 15, line 40; figures 3A, 3B, 4A & 4B). As shown

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in figure 4B, the system taught by Handique comprises a thermopneumatic actuating system denoted by 180, a hydrophobic gas vent (170), and an outlet, which is located to the right of the sample (160) and at the end of the channel containing the sample, from which the sample is transferred for further processing, such as to a lysing chamber for cell lysing, when integrated within an analytical microfluidic system.



Hence, as evidenced by Handique, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating such a thermopneumatic fluid transport system with a microfluidic apparatus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a thermopneumatic fluid transport system with a microfluidic apparatus for facilitating effective sample fluid transport.

Furthermore, regarding claims 16, 21, 25 & 39, Pourahmadi in view of Handique teaches the additional incorporation of a positioning element (e.g., a hydrophobic region 140) and a thermopneumatic actuator downstream of the lysing chamber 119 for facilitating sample fluid flow within the apparatus for further processing (see figure 2). Pourahmadi teaches that the lysed sample proceeds from the lysing chamber 119 down channel 121 and is forced to flow through a capture component 122 (see paragraph 0070; figure 2). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a fluid motive source, such as the thermopneumatic system of Handique, within the apparatus of Pourahmadi to facilitate effective sample fluid transport (see MPEP § 2144.07). As discussed above, as evidenced by Handique, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating such a thermopneumatic fluid transport system with a microfluidic apparatus (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a secondary thermopneumatic fluid transport system with a microfluidic apparatus as claimed for facilitating effective sample fluid transport.

Regarding claims 2, 4, 17 & 19, these claim recitations are considered process or intended use limitations.

Regarding claims 3, 4, 18 & 19, Pourahmadi teaches the incorporation of a cell lysis mechanism utilizing an electrical field to facilitate cell lysis and extraction (see paragraph 0112).

Regarding claims 14 & 39, Handique suggests the incorporation of valves, which are well known in the art, with the hydrophobic vents (70 & 170) for opening and closing the vents for facilitating sample fluid transport (see col. 14, lines 51 – 57; figures 3A, 3B, 4A & 4B) (see MPEP 2144.03). In addition, Pourahmadi teaches the incorporation of various valves within the

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disclosed microfluidic apparatus (see, e.g., paragraph 0052). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a plurality of valves within the apparatus as claimed in order to facilitate effective sample fluid flow within apparatus.

Regarding claim 22, Handique teaches that the various features of the microfluidic apparatus are microfabricated and integrated within silicon and glass substrates (see col. 3, line 46 – col. 4, line 10). Pourahmadi also teaches that the disclosed apparatus is microfabricated utilizing glass or silicon structural members as well (see paragraphs 0097 & 0098). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in microfabricating an integrated microfluidic apparatus as claimed (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to microfabricate an integrated microfluidic apparatus as claimed.

Regarding method claims 27 – 30, 32, 33, 35 – 37 & 40 – 44, as discussed above, Pourahmadi in view of Handique teaches all of the positively recited structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). Furthermore, when the structure recited in a reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Pourahmadi and Handique, as such is the intended operation of that apparatus.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered, but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian J. Sines". The signature is stylized with a large, looping initial "B" and a trailing flourish.